K090222

## 3.0 Summary of Safety and Effectiveness Information

APR 2 8 2009

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| Sponsor: | Pioneer Surgical Technology<br>375 River Park Circle<br>Marquette, MI 49855<br>(906) 226-4812<br>Contact: Jonathan M. Gilbert |
| Device Name: | Pioneer Lumbar Plate System |
| Classification Name: | Spinal Intervertebral Body Fixation Orthosis |
| Classification Number: | Regulation Number: 888.3060<br>Product Code: KWQ; Panel Code: 87 |
| Description: | The Pioneer Lumbar Plate System consists of an assortment of plates and screws. The system also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification. Implants are composed of titanium alloy Ti6Al4V (ISO 5832-3) ELI, the same as predicate device. |
| Intended Use: | The Pioneer Lumbar Plate System is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. The Pioneer Lumbar Plate System is indicated as an adjunct to fusion in the treatment of lumbar and lumbosacral (LI -S1) spine instability as a result of the following: fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, and failed previous spine surgery.<br><br>Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. |
| Performance Data: | Mechanical testing in accordance with the "Guidance for Industry and FDA Staff. Guidance for Spinal Systems 510(k')s", May 3, 2004 is presented. |
| Performance and SE Determination: | Comparisons of device performance data, materials, indications and design/function to predicate devices, K063158 &K041167, were provided in making a determination of substantial equivalence. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pioneer Surgical Technology
% Mr. Jonathan M. Gilbert
375 River Park Circle
Marquette, Michigan 49855

APR 2 8 2009

Re: K090222
Trade/Device Name: Pioneer Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 13, 2009
Received: March 16, 2009

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## *Indications: 2.0 Indications for Use Statement*

510(k) Number (if known): K090222

Device Name: Pioneer Lumbar Plate System

Indications: The Pioneer Lumbar Plate System is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. The Pioneer Lumbar Plate System is indicated as an adjunct to fusion in the treatment of lumbar and lumbosacral (LI -S1) spine instability as a result of the following: fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, and failed previous spine surgery.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use ___√___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of General, Restorative, and Neurological Devices

510(k) Number K090222